REMARKS

I. Status of the Claims

Claims 2-4 and 7-10 have been cancelled without prejudice, waiver or disclaimer. Claim 1 has been amended to recite "... lowering of LDL cholesterol by at least forty percent from baseline." New claims 11-13 are similar to claims 1, 5, and 6 but differ in that they recite "...lowering of LDL cholesterol by about fifty percent or more from baseline." Support for the amendment to claim 1 and new claims 11-13 can be found on page 5, lines 12-15 and lines 19-22 of the Specification. No new matter has been added by the present amendment. Upon entry of this amendment, Claims 1, 5-6, and 11-13 will be pending.

II. Rejection Under 35 USC 112, first paragraph

Claims 1, 5 and 6 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection in view of the present amendment to the claims.

As set forth in MPEP 2163.02, the standard for determining compliance with the written description requirement is as follows:

> Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

The specification as-filed provides full written description support for pending claims 1, 5, 6, and 11-13. The claimed invention is directed to methods for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease in need of

such treatment consisting of administering atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol by at least forty percent from baseline. Example 1, beginning on page 7 of the Specification, illustrates that aggressive lowering of LDL with a cholesterol lowering agent (e.g. atorvastatin) is effective to prevent or delay the need for catheter-based revascularization. *See also* page 25, lines 5-24 of the Specification. The Written Description requirement is fully met. Applicant respectfully requests this rejection be withdrawn.

III. Rejection Under 35 USC 103

Claims 1, 5 and 6 stand rejected under 35 USC 103 as being unpatentable over Seed et al., US Patent No. 5,861,399, in view of Bocan, WO 97/16184. Applicant respectfully traverses this rejection.

Applicant's claimed invention is directed to a method for preventing or delaying catheter-based revascularization in patients suffering from coronary artery disease in need of such treatment consisting of administering atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol by at least forty percent from baseline (Claims 1, 5 and 6) or by about fifty percent or more from baseline (Claims 11-13). The cited references, alone or in combination, fail to teach or suggest Applicant's claimed invention with any reasonable expectation of success.

Seed is directed to a method for treating inadequate myocardial function in a mammal that involves administering to the mammal a combination including (a) a compound that includes eicosapentaeneoic acid or docosahexaeneoic acid and (b) a cholesterol synthesis or transfer inhibitor, in combination with dietary restrictions. Seed, Col. 2, lines 8-14. Thus the method of Seed relies on the administration of a combination of at least two compounds (a) and (b). Seed further states that the combination of compounds (a) and (b) is key:

> Although the literature contains many references to the use of one or several of the medication components described herein, there has been no description to date of a treatment program which combines aggressive cholesterol lowering with marine lipid loading. This combination is shown here to promote rapid and enduring improvement in myocardial function. Seed, Col. 1, line 66 through Col. 2, line 5.

In addition, Seed is also directed to a method for reducing a coronary artery stenosis by at least 20% based on the specific combination of (1) administration of a cholesterol-lowering therapeutic and (2) dietary restrictions. Seed, Col. 2, lines 62- Col. 3, line 1.

In contrast, Applicant's claimed methods do not rely on a specific combination but rather consist of administration of atorvastatin or a pharmaceutically acceptable salt thereof. As set forth in MPEP 2111.03, the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim.

Bocan fails to remedy the deficiencies of Seed.

Bocan, like Seed, is also directed to methods which rely upon a combination of two compounds; in this instance, an ACAT inhibitor and a HMG-CoA reductase inhibitor. *See* Abstract and Summary of the Invention on page 2 of Bocan. Thus, for reasons given for Seed, Bocan alone would not render Applicant's claimed inventon obvious. Furthermore, Seed in view of Bocan would not render Applicant's claimed invention obvious.

Bocan describes atorvastatin as a HMG-CoA reductase inhibitor. However, the use of the atorvastatin of Bocan in the method of Seed would also not render Applicant's claimed invention obvious as such a modification would still not teach or suggest Applicant's claimed invention, much less with any reasonable expectation of success.

Since Seed and Bocan, each alone or in combination, depend on specific combinations not found in Applicant's claimed invention. Applicant's claimed invention is not obvious in view of the cited references. Applicant respectfully requests this rejection be withdrawn.

IV. Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the above amendment and remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 23-0455. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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